CARELLA, BYRNE, CECCHI, OLSTEIN, BRODY & AGNELLO, P.C.
COUNSELLORS AT LAW

CHARLES C. CARELLA
BRENDAN T. BYRNE
PETER G. STEWART
JAN ALAN BRODY
JOHN M. AGNELLO
CHARLES M. CARELLA
JAMES E. CECCHI

JAMES D. CECCHI (1933-1995)
JOHN G. GILFILLAN III (1936-2008)
ELLIOT M. OLSTEIN (1939-2014)

JAMES T. BYERS
DONALD F. MICELI
A. RICHARD ROSS
CARL R. WOODWARD, III
MELISSA E. FLAX
DAVID G. GILFILLAN
G. GLENNON TROUBLEFIELD
BRIAN H. FENLON
LINDSEY H. TAYLOR
CAROLINE F. BARTLETT

5 BECKER FARM ROAD
ROSELAND, N.J. 07068-1739
PHONE (973) 994-1700
FAX (973) 994-1744
www.carellabyrne.com

RICHARD K. MATANLE, II
FRANCIS C. HAND
AVRAM S. EULE
RAYMOND W. FISHER

OF COUNSEL

RAYMOND J. LILLIE
WILLIAM SQUIRE
ALAN J. GRANT°
STEPHEN R. DANEK
DONALD A. ECKLUND
MEGAN A. NATALE
ZACHARY S. BOWER+
MICHAEL CROSS
CHRISTOPHER J. BUGGY
JOHN V. KELLY III
°MEMBER NY BAR ONLY
+MEMBER FL BAR ONLY

June 19, 2019

CONTAINS INFORMATION DESIGNATED BY PLAINTIFF AS HIGHLY CONFIDENTIAL—FILED UNDER SEAL

Via ECF and Federal Express
Hon. Michael A. Hammer, U.S.M.J.
Martin Luther King Building
& U.S. Courthouse
50 Walnut Street
Newark, NJ 07101

Re: *Celgene Corp. v. Hetero Labs Ltd.*, C.A. No. 2:17-3387-ES-MAH (consolidated)

Dear Judge Hammer:

This firm, together with Taft Stettinius & Hollister LLP, represents Defendants Apotex Inc. and Apotex Corp. (collectively, "Apotex"). We write to respectfully request an order from this Court compelling Plaintiff Celgene Corporation ("Celgene") to produce a settlement agreement involving the patents-in-suit that Celgene recently entered into with Synthon Pharmaceuticals Inc., Synthon B.V., and Synthon S.R.O. (collectively "Synthon"), and Alvogen Pine Brook LLC ("Alvogen") (Synthon and Alvogen collectively, "Synthon/Alvogen"), in connection with *Celgene Corporation v. Synthon Pharmaceuticals Inc., et al.*, C.A. Nos. 18-10775 and 19-9737 (ES)(MAH) (D.N.J.) ("Celgene-Synthon/Alvogen settlement agreement" or "settlement agreement").

Celgene refuses to produce the Celgene-Synthon/Alvogen settlement agreement on relevance, disproportionality, and confidentiality grounds. However, as explained below, this Court and numerous others have routinely found settlement agreements entered into between a patent owner and an accused infringer's competitors to be discoverable, and have serially rejected the objections Celgene raises here. *See, e.g., Wyeth v. Orgenus Pharma Inc.*, C.A. No. 09-3254 (FLW), 2010 WL 4117157, at *4 (D.N.J. Oct. 19, 2010) (ordering production of settlement agreements that brand plaintiff entered into with third party generic competitors after finding the agreements relevant to at least obviousness and potential patent misuse, and that "[p]laintiff's third party confidentiality concerns d[id] not outweigh legitimate grounds to compel production"); *Pfizer Inc. v. Apotex Inc.*, 731 F. Supp. 2d 754, 758-762 (N.D. Ill. 2010) (finding brand plaintiff's settlement agreement with generic defendant's competitors relevant to obviousness, commercial success, and potential patent misuse, and ordering production); *Allergan, Inc. v. Teva Pharm. USA, Inc.*, No. 2:15-cv-1455-WCB, 2017 WL 132265, at *1-2 (E.D. Tex. Jan. 12, 2017) (Bryson, J., sitting by designation) (finding brand settlement agreement

relevant to at least obviousness and commercial success, and rejecting brand's argument that it did not plan on relying on the agreement for commercial success).

Because the discoverability of such settlement agreements is well settled, Apotex respectfully request that this Court order Celgene to produce to Apotex the Celgene-Synthon/Alvogen settlement agreement.

I. BACKGROUND

Celgene began instituting these consolidated actions against Defendants[1] in May of 2017. ECF No. 1, Compl.; *see also*, 17-cv-3159 ECF No. 1, Compl. After the commencement of fact discovery, Defendants served Rule 34 requests for production on Celgene, including Defendants' Request for Production ("RFP") No. 59:

> All Documents and things concerning any licensing agreement, any negotiations and preparation for negotiations that were conducted prior to entering into any license agreement, any offer to license, or solicitation of a license, involving the patents-in-suit and related patents, relating to any generic or authorized generic version of Pomalyst®.

Ex. A, Celgene's Objections and Resp. to Defs.' RFP No. 59. In response, Celgene lodged objections based on alleged lack of relevance, disproportionality, overbreadth, third party confidentiality, and privilege. *Id*.

In 2018, Celgene began filing actions against Synthon and Alvogen, generic competitors of Defendants in this case, asserting infringement of the same patents at issue in this case. *See* 18-cv-10775 ECF No. 1, Compl.; 19-cv-9737 ECF No. 1, Compl.; ECF No. 1, Compl.; *see also, e.g.*, 18-cv-16395 ECF No. 1, Compl. On May 9, 2019, Celgene notified this Court that it had reached settlement with Synthon and Alvogen. Ex. B, May 9, 2019 Ltr. from Celgene to the Court (18-cv-10775 ECF No. 50).

On May 10, 2019, Defendants approached Celgene regarding the Celgene-Synthon/Alvogen settlement agreement and documents related to the agreement,[2] pointed out that they were responsive to at least Defendants' RFP No. 59, explained relevancy based on at least invalidity and unenforceability of the patents-in-suit, and based on the relief Celgene seeks against Defendants, and requested that Celgene produce the settlement agreement documents.

[1] "Defendants" refers to all defendants in the instant consolidated actions, and includes Apotex; Aurobindo Pharma Limited, Aurobindo Pharma USA, Inc., Aurolife Pharma LLC, Eugia Pharma Specialties Limited, Breckenridge Pharmaceutical, Inc., Hetero Labs Limited, Hetero Labs Limited Unit-V, Hetero Drugs Limited, Hetero USA, Inc., Mylan Pharmaceuticals Inc., Mylan Inc., Mylan, N.V., and Teva Pharmaceuticals USA, Inc.

[2] Apotex has since narrowed the scope of the documents it seeks to the Celgene-Synthon/Alvogen settlement agreement only.

Ex. C, May 10, 2019 email from R. Shrestha and F. Calvosa. Despite following up with Celgene on two separate occasions, Celgene refused to respond to Defendants' request, and it was not until a May 31, 2019 teleconference between counsel for Apotex and counsel for Celgene on a separate matter—three weeks after Defendants originally approached Celgene on the settlement agreement documents—that Celgene promised a response by the end of the first week of June. Ex. C, May 31, 2019 email from R. Shrestha to F. Calvosa.

On June 6, 2019, nearly a month after Defendants first approached Celgene on this issue, Celgene responded that it "d[id] not agree with Defendants' position," without elaborating any further, and offered to meet and confer on the issue. On June 14, 2019, the parties met and conferred. Apotex explained that the settlement agreement was relevant to the invalidity of the patents-in-suit—particularly obviousness and secondary considerations—as well as potential patent misuse. Celgene steadfastly objected to the production on relevance, disproportionality, and confidentiality grounds, and vehemently disputed whether Apotex would have any standing to raise a patent misuse defense based on Celgene's activities with Synthon and Alvogen. At the conclusion of the call, Celgene stated that it would "reconsider" the issue. Apotex followed up the meet and confer with an email reminding Celgene: (1) that this dispute had been pending for over a month, including three weeks where Celgene refused to respond to Defendants' initial inquiry on the topic; and (2) of Celgene's statutory obligation to reasonably cooperate in expediting this action (*see* 21 U.S.C. § 355(j)(5)(B)(iii)), and requested a final response from Celgene by June 19, 2019. Ex. C, June 14, 2019 email from R. Shrestha to F. Calvosa. On June 19, Celgene responded that it continued to disagree with Defendants' relevance arguments, and that it would oppose any motion to compel filed.

II. ARGUMENT

The overwhelming case law on this topic is clear and the issue is well-settled: settlement agreements entered into between a plaintiff patent owner and an accused infringer's competitors that involve the same patents are relevant to multiple issues—including patent invalidity, unenforceability, and remedies—and third party confidentiality concerns are insufficient to shield the agreements from production. *See, e.g., Wyeth*, 2010 WL 4117157, at *4 (noting "that other courts have routinely recognized" the discoverability of such agreements, and identifying numerous Federal Circuit and District Court decisions ordering production of such agreements).

A. Relevance

1. Patent Invalidity—Secondary Considerations

Defendants have raised invalidity defenses and counterclaims to the patents-in-suit, including based on obviousness. *See, e.g.*, ECF No. 22, Apotex's Answer, Defenses, and Countercls. at First through Fourth Additional Defense; *id*. at Countercls. Count Nos. VII, XIII, XV, and XVII. In response, Celgene has asserted that the patents-in-suit are non-obviousness because of, *inter alia*, secondary considerations, including that the alleged commercial embodiment of the patents-in-suit—Celgene's Pomalyst®—is commercially successful. Secondary considerations are the "circumstances which preceded, attended and succeeded the

appearance of the invention," which may be probative of the non-obviousness of a challenged patent. *Crocs, Inc. v. Int'l Trade Comm'n*, 598 F.3d 1294, 1310 (Fed Cir. 2010) (quotations and citations omitted). Secondary considerations include commercial success, licensing of the patent-in-suit, long-felt but unresolved needs, and failure of others. *See Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966); *EWP Corp. v. Reliance Universal Inc.*, 755 F.2d 898, 907 (Fed. Cir. 1985). Celgene must prove a nexus between any secondary considerations it relies on and "what is both claimed and *novel* in the claim." *In re Kao*, 639 F.3d 1057, 1068 (Fed. Cir. 2011).

Here, if the Celgene-Synthon/Alvogen settlement agreement includes a license to any of the patents-in-suit, that license itself may be probative of non-obviousness. *EWP*, 755 F.2d at 907 (considering licensing but finding the claimed invention obvious nonetheless). Apotex is entitled to secure production of the settlement agreement regardless of whether Celgene will or will not rely on the license. *Pfizer*, 731 F. Supp. 2d at 759.

Moreover, the Celgene-Synthon/Alvogen settlement agreement is relevant to commercial success. *Allergan*, 2017 WL 132265, at *2 ("[T]he settlement agreement is potentially relevant to commercial success regardless of whether Allergan plans to exploit it."); *see also, Pfizer*, 731 F. Supp. 2d at 759; *AbbVie Inc. v. Boehringer Ingelheim Int'l GmbH*, No. 17-cv-01065-MSG-RL, 2019 WL 1571666, at *3 (D. Del. Apr. 11, 2019). Any license contained in the settlement agreement may itself be relevant to commercial success. *See Datapoint Corp. v. PictureTel Corp.*, No. 3:93-CV-2381, 1998 WL 51356, at *2 (N.D. Tex. Jan. 23, 1998). Moreover, information in the settlement agreement may bear on nexus; for instance, if the settlement agreement contains a license to the earlier expiring method of treatment ("MOT") patents, but no license to the later expiring formulation patents (only a covenant-not-to-sue based on those), this may be evidence that any commercial success is tied to the MOT patents and lacks nexus to the formulation patents. *Pfizer*, 731 F. Supp. 2d at 759.

2. Patent Misuse

"Patent misuse is a defense to claims of infringement, which, if successful, renders a patent unenforceable until the misuse is 'purged.'" *Pfizer*, 731 F. Supp. 2d at 759 (citing *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1372 (Fed. Cir. 1998)). Patent misuse prohibits the patentee from "us[ing the patent] to acquire a monopoly not embraced in the patent." *Princo Corp. v. Int'l Trade Comm'n*, 616 F.3d 1318, 1327 (Fed. Cir. 2010). The most common form is "requiring the purchase of an unpatented product as a condition for obtaining a license to the patent." *Id.* Another form is "requiring the payment of licensing fees after the expiration of the licensed patent." *Id.* Contrary to the understanding of Celgene's counsel, "a party invoking the doctrine need [not] demonstrate . . . that the alleged misuse has resulted in injury to the party itself." *Robintech, Inc. v. Chemidus Wavin, Ltd.*, 450 F. Supp. 817, 819 (D.D.C. 1978) (citing, *inter alia*, *Morton Salt Co. v. G.S. Suppiger, Co.*, 314 U.S. 488, 490, 494 (1942), *abrogated on other grounds by Ill. Tool Works Inc. v. Indep. Ink, Inc.*, 547 U.S. 28, 42-43 (2006)).

Here, if the settlement agreement shows that Celgene conditioned a license in the patents-in-suit on Synthon and Alvogen purchasing the active pharmaceutical ingredient—pomalidomide, which is unpatented—from Celgene, that could give rise to a defense of patent

misuse for Apotex. Moreover, if any license granted demands royalties past the expiration of the patents-in-suit, that may also form the predicate of a patent misuse defense for Apotex. This Court and others have found settlement agreements entered into between a patent owner and an accused infringer's competitors relevant to a potential patent misuse defense. *Wyeth*, 2010 WL 4117157, at *4; *Pfizer*, 731 F. Supp. 2d at 759-60.

3. Injunctive Relief

Celgene seeks permanent injunctive relief against Defendants. *See, e.g.*, ECF No. 1, Compl. at Prayer for Relief Against Apotex. To secure injunctive relief against Defendants under 35 U.S.C. § 271(e)(4)(B), Celgene will need to prove irreparable harm. *Ebay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 393-94 (2006); *see also*, *Pfizer*, 731 F. Supp. 2d at 760-62 (*Ebay* applies to § 271(e)(4)(B)). Evidence that Celgene has licensed the patents-in-suit for a certain royalty rate may undercut any attempt it makes to prove irreparable harm, as such evidence would arguably show the adequacy of damages to remedy infringement. *See, e.g., i4i L.P. V. Microsoft Corp.*, 598 F.3d 831, 862 (Fed. Cir. 2010).

B. Disproportionality

The Celgene-Synthon/Alvogen settlement agreement is a discrete, easily identifiable document, likely less than 50-pages long, and likely negotiated within the last few months by Celgene's litigation counsel in this case; producing it will be no burden to Celgene whatsoever. *See AbbVie*, 2019 WL 1571666 at *2 (settlement agreements "are easily identifiable and producible without undue burden").

C. Third Party Confidentiality

This Court and others have routinely rejected attempts by a producing party to shield from production documents based on alleged third party confidentiality, including in the context of settlement agreements in patent cases. *See, e.g.*, *Wyeth*, 2010 WL 4117157, at *4. Moreover, there is a protective order entered in this case. ECF No. 152.

III. CONCLUSION

Apotex respectfully requests that the Court order Celgene to produce the Celgene-Synthon/Alvogen settlement agreement, and thanks the Court for its attention to and consideration of this request.

Respectfully submitted,

CARELLA, BYRNE, CECCHI,
OLSTEIN, BRODY & AGNELLO

/s/ Melissa E. Flax

MELISSA E. FLAX

Attachments
Cc: All Counsel of Record (w/attachments)(via email)